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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,107	10/14/1999	PETER KUFER	3816-4000	6846
26161	7590	01/27/2005	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			HELMS, LARRY RONALD	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/403,107

**Applicant(s)**

KUFER ET AL.

**Examiner**

Larry R. Helms

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 18,19,22,28,29,31,32,38,39,42,53-56 and 65-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18,19,22,28-29, 31, 32, 38-39, 42, 53-56, 65, 67-68 is/are rejected.
- 7) ☒ Claim(s) 66 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/23/04 has been entered.
2. Claims 18-19, 22, 28-29, 31-32, 38-39, 42, 53-56, 65-68 are pending and under examination.
3. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
4. The following Office Action contains NEW GROUNDS of rejection.

### ***Rejections Withdrawn***

5. The rejection of claims 18-19 under 35 U.S.C. 102(b) as being anticipated by Hoess et al (Proceedings of the American Association for Cancer Research 38page 30 abstract 198, 1997, lds #3) is withdrawn in view of arguments presented in the response of 10/18/04.

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6. The rejection of claims 18-19, 22, 28, 29, 31, 32, 38-39, 42, 53-56, 65-67 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendments to the claims.

7. The rejection of claims 18-19 under 35 U.S.C. 103(a) as being unpatentable over Hoess et al (Proceedings of the American Association for Cancer Research 38 page 30 abstract 198, 1997, Ids #3) is withdrawn in view of the arguments presented in the response filed 10/18/04.

### ***Response to Arguments***

8. The rejection of claims 22 and 42 and newly added claim 68 under 35 U.S.C. 112, first paragraph, is maintained and made again.

The response filed 10/18/04 has been carefully considered but is deemed not to be persuasive. The response states that what the examiner appears to overlook is the existence of functional antibodies and starting with functional antibodies it would require only routine experimentation to modify two of the three CDRs (see page 6 of the response). In response to this argument, while the claims depend from claim 18 which requires antibodies recognizing the human 17-1A antigen, the claims 22 and 42 only define one CDR in each chain and the other four CDRs can be anything and as such it would be undue experimentation to obtain four other CDRs to combine with any one of the CDRs in each chain in order to make a complete antibody that would have the required binding from the myriad of CDRs in the human B lymphocytes or B cell repertoire. Claim 68 is included in this rejection because of the indefinite nature of the

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claim (see 112 second below) it is unclear if the CDRs are from the nucleic acid sequence that encodes framework regions or from just any three segments in the recited sequence and as such one skill in the art would not conclude that just any three segments in the recited sequences could be used to make a functional antibody.

Therefore the specification has not enabled antibodies with one specified CDR sequence and any five CDRs from any other antibody. Therefore the rejection is maintained.

9. The rejection of claims 18-19, 28-31, 38-39, 53-55, 65, 67 under 35 U.S.C. 103(a) as being unpatentable over Kucherlapati et al (U.S. Patent 6,150,584, filed 10/96) as applied to claims 18-20, 34-40, 43-45, 48-50, 65, 67 above, and further in view of Gottlinger et al (Int. J. Cancer 38:47-53, 1986, IDS #3) is maintained.

The response filed 10/18/04 has been carefully considered but is deemed not to be persuasive. The response states that the human antibodies in the '584 patent undergo affinity maturation and are not from unprimed mature B cells and would not be low or not immunogenic in humans. In response to this argument, Claim 18 requires VH and VL derived from unprimed mature human B-lymphocytes and as such the antibodies of the prior art would meet this limitation because even if they are from somatic mutations this would still be derived from unprimed cells. The method of the '584 patent results in the genes for the antibodies being identical to those of a human repertoire and as such the antibody produced would obviously have low immunogenicity in humans .

***The following are NEW GROUNDS of rejections***

***Claim Rejections - 35 USC § 112***

10. Claim 68 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 68 is indefinite because it is not clear if the three CDRs are encoded by just any three segments, for example are the framework regions or only the regions that encode the CDR regions used for the antibody?

11. Claims 32 and 56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Claim 32 was amended in the response filed 1/2/03 to add the limitations "SEQ ID NO:143 and/or 145". The response did not apparently state where support for the limitation can be found. On pages 13-14 and 16 of the specification it appears that there is support for a VH that comprises one of the sequences in Figure 7 and 8 and/or a VL of Figure 6 and 9. There is no support for the VH being from both 7 and 8 at the

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same time or in the same molecule. Applicant is required to provide specific support for the limitation in the specification as originally filed or remove it from the claim.

### ***Conclusion***

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Respectfully,

Larry R. Helms Ph.D.

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571-272-0832

LARRY R. HELMS, PH.D  
PRIMARY EXAMINER



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